REMARKS

Claims 15-26 are pending in the application. Claim 15 is an independent claim. A Supplemental Information Disclosure Statement is submitted herewith.

Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The rejection proffers that claim 15 is vague because it is unclear what reagents, if any, are in the detection zone that would enable it to detect the analyte. It is proposed that claim 15 be amended to recite that the detection zone is the last zone of the element that allows liquid transport and that it is devoid of a binding reagent that would enable detection of the analyte. Support for claim 15 is provided at page 4, lines 1-14, page 14 last paragraph to page second paragraph, section F of example 1 (page 25) of the specification as filed and Figures 1-4.

The detection zone in the element simply *does not* operate by having binding reagents for the analyte. Instead, the detection zone functions because any labeled material that has not been trapped by the previous zones travels to the detection zone. Since the detection zone is the last zone in the element that allows liquid transport, the liquid transport stops once the detection zone is filled with liquid. This means that any visually detectable-labeled binding partner that has been bound to an analyte molecule travels to the detection zone, but does not emerge from it. Accordingly, any direct visually detectable label that reaches the detection zone carries out the determination of the analyte in the detection zone as recited by claim 15.

The claim as amended is believed to be sufficiently definite for purposes of 35 U.S.C. 112, second paragraph. Claims 16-26 depend from amended claim 15. In light of the amendment, reconsideration of the rejection leading to its withdrawal is respectfully requested.

Claims 15-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al. (US 4,230,683). The rejection proffers that it would have been obvious . . . to modify the device of Fitzpatrick et al. by

using the hapten-labeled method of Decker et al. The rejection is respectfully traversed for the reasons set forth below:

1. With no binding reagent being present in the detection zone, amended claim 15 differs from the disclosures of the cited references alone or in combination with one another. The Examiner's statement that Fitzpatrick discloses a detection zone that contains "immobilized receptor that will bind the labeled-receptor/analyte complex enabling their detection therein" is acknowledged. It is further noted that Fitzpatrick teaches the importance of the presence of an immobilized binding partner in the detection zone (see column 8 line 58 to column 9 line 15). Claim 15 of the present invention as amended recites that the detection zone is devoid of a binding reagent that would enable detection of the analyte.

Decker et al. fails to cure the inadequacies of Fitzpatrick et al. Specifically, Decker teaches an immunoassay method that includes "reacting the antigen or antibody *bound* to the solid support with a hapten conjugated antibody to the antigen or antibody to be detected to provide hapten conjugated antibody *bound* to the solid support, reacting hapten conjugated antibody *bound* to the solid support with labeled anti-hapten antibody, and measuring the labeled hapten antibody *bound* to the solid support (see column 2 lines 4-14, *emphasis added*). Claim 15 states that the detection zone is devoid of a binding reagent that would enable detection of the analyte. Therefore the cited references alone and/or in combination with one another fail to disclose or suggest the element of claim 15.

2. It is submitted that Fitzpatrick et al. and Decker et al. when applied alone or in combination with one another, fail to disclose or suggest an element that comprises a universal conjugate as recited by claim 15. Contrary to the Examiner's stated assumptions (page 7, third paragraph of the Office Action), it is noted that Applicants *do not* agree that the labeling system taught by Decker et al. is the same as that of claim 15.

The Examiner's statement that "Fitzpatrick differs from the claimed invention in failing to teach a universal conjugate" is acknowledged. The statement (page 6 line 19 of the

Office Action mailed June 17, 2004) that "Decker teaches the universal conjugate system" is respectfully traversed.

It is true that Decker et al. teaches a conjugate system, but one that is quite different from that required by the element of claim 15. Applicants' universal conjugate comprises "a second bioaffine binding partner and a second visually detectable label". No such universal conjugate is taught or suggested by Decker et al. In contrast, Decker et al. discloses second conjugates with radioactive, enzyme or fluorescence labels.

With Decker et al. lacking a universal conjugate comprising a direct visually detectable label, its combination with Fitzpatrick et al. fails to lead to the presently amended claim 15. Specifically, starting with the disclosure of Fitzpatrick et al., a person skilled in the art would at best be motivated to replace the binding partner labeled with a direct visually detectable label with the labeling system as described by Decker et al. However, the labeling system of Decker et al. is silent with respect to direct visually detectable labels. Combination of these references would therefore lead to a test device that is significantly different from the element of claim 15. Specifically, no direct visually detectable label would be present, but instead radioactive, enzyme or fluorescence labels would be present. This is clearly not what is claimed in the presently amended claim 15.

The element of claim 15 simply runs contrary to the teaching of both Fitzpatrick et al. and Decker et al. First, Fitzpatrick et al.'s teaching of a direct label - not requiring a secondary reaction or instrument for detection (Column 4 lines 32-33) was not followed by Applicants. The use of a direct label method was recognized by Applicants to create a variety of problems. Specifically, when direct labels are used with a bioaffine binding partner that varies according to the analyte, optimal conditions have to be created on the analytical element for reaction and storage. This individual adaptation to the analyte to be determined is very laborious. Difficulties include stability and varying spatial arrangements that can lead to steric problems when such conjugates are reacted with the analyte and can thus result in poor sensitivity.

Second, Decker et al.'s teaching of a hapten-labeled method – requiring (^{125}I, enzymes, and fluorescent chemicals) for measurement of the antigen or antibody from the test sample was not followed by Applicants. The use of making non-visible labels, such as enzyme labels, visible was recognized by Applicants in the specification as filed to also create a variety of additional problems. Specifically, the disadvantages making a label visible are a complication, costly, and my result in technical difficulties when the corresponding enzyme substrate has stability problems.

Accordingly, claim 15 runs contrary to both the teachings of Fitzpatrick et al. and Decker et al. either alone or in combination with one another. Claim 15 specifically recites a conjugate that comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and a universal conjugate that comprises a second bioaffine binding partner and a visually detectable label. Thus, claim 15 avoids the difficulties posed by each of the cited references by providing an element with reagents that can be produced simply and reproducibly.

In light of the above, it is submitted that Fitzpatrick et al. and Decker et al. when taken as a whole, fail either alone or in combination to disclose or suggest an element comprising "a sample application zone, a detection zone located downstream from the sample application zone and being the last zone of the element that allows liquid transport, the detection zone being devoid of a binding reagent that would enable detection of the analyte; a zone containing immobilized analyte or analyte analogue . . . a material that enables liquid transport between the zones, a conjugate impregnated in a matrix material located upstream of the zone containing immobilized analyte or analyte analogue, the conjugate can be detached from the matrix material by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and a universal conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner and a second detectable label, the second

bioaffine binding partner is capable of a specific binding reaction with the first detectable label, wherein the second detectable label is a direct visually detectable label formed to carry out the determination of the analyte in the detection zone", as required by amended claim 15. Claims 16-17 and 20-23 depend from claim 15.

It is respectfully submitted that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

Claims 18, 19, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al. in view of Decker et al. as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268). Fitzpatrick et al. and Decker et al. have been discussed above with reference to independent claim 15. As discussed above, it is submitted that neither Fitzpatrick et al. nor Decker et al. either alone or in combination with one another disclose or suggest the element of claim 15. Claims 18, 19 and 24-26 depend from independent claim 15.

Bernstein et al. discloses a test strip having three zones – a reaction zone coated with a substance that binds the analyte, a sample zone with a region for addition of the sample of solution or fluid, and a detection zone with a region coated with detection reagent. Bernstein et al. fails to cure the inadequacies of Fitzpatrick et al. and Decker et al. It is therefore respectfully submitted that Bernstein et al. cannot be said to provide suggestion or motivation to modify Fitzpatrick et al. and Decker et al. to meet the requirements of dependent claims 18, 19, and 24-26.

Accordingly, it is submitted that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Reconsideration of the rejection of the claims and withdrawal of the rejection is respectfully requested.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that any fees due be charged to Deposit Account Number 50-0877 with reference to (BMID 9941 US).

Respectfully submitted,

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Jill L. Woodburn, Reg. No. 39,874
The Law Office of Jill L. Woodburn, L.L.C.
128 Shore Drive
Ogden Dunes, IN 46368-1015
Telephone No.: 219-764-4005
Facsimile No.: 219-764-4070